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(54) Title: IL-7 DRUG SUBSTANCE, COMPOSITION, PREPARATION AND USES

(57) Abstract: The present invention relates, generally, to the fields of immunology and molecular biology. The invention discloses, more particularly, new and improved interleukin-7 drug substances, corresponding specific immunoreactive antibodies, as well as compositions comprising the same, their preparation and uses. The invention also discloses methods to characterize the impurity profile of a r-hIL-7 drug substance used for therapeutic purpose, as well as optimized nucleotide sequences encoding mammalian IL-7, recombinant expression vectors and methods for preparing and purifying said polypeptides. The present invention stems from the unexpected discovery that the long term activity of recombinant IL-7 is mostly expressed by a specific conformer and that other conformers, potential product-related substances, product-related impurities, and process-related impurities, which would normally be included in the specification of the drug substance and/or drug product, although bioactive, should be strictly minimized because they are able to trigger an immune reaction against the desired IL-7 molecule.

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